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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of:

OCT 0 1 2000 Some n NIELSEN, et al.

rial No.: 09/845,716

Filed: May 2, 2001

For: USE OF A-MSH and EPO...

Art Unit:

Examiner:

Washington, D.C.

October 1, 2001

Docket No.: NIELSEN3A

## INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

## Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- 1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:
- [ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b).
- [X] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).
- [ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "i" below). See 37 CFR 1.97(c).
  - [ ] i. Counsel certifies that, upon information and

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belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- [] ii. A check for the fee set forth in 1.17(p), presently believed to be \$180, is enclosed (check no. \_\_\_\_\_).
- after (A), D. (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A check for the fee set forth in 1.17(i)(1), presently believed to be \$130 is enclosed \_\_\_\_\_). Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- [ ] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR \$1.129(a). Pursuant to MPEP \$706.07(g), page 700-46, col. 2 (February 2000), this IDS is treated as if filed with a period set forth in 37 CFR \$1.97(b) and considered without the petition and petition fee required by 1.97(d).
  - 2. In accordance with 37 C.F.R. 1.98, this IDS

includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

- [ ] A. Documents \_\_\_\_\_ are deemed substantially cumulative to documents \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- [ ] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under \$1.97 must contain a "list of all patents, publications or other information submitted consideration by the Office", see \$1.98(a) (1),requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 (MPEP §609 merely says that use of this form is "encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in

a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

- [X] 3. Documents  $\underline{AH}$  and  $\underline{AL}$  are not in the English language. In accordance with 1.98(c), Applicants state:
  - [X] document AH already contains an English language abstract, summary or claim set.
  - [ ] a publicly available abstract is attached to each of documents \_\_\_\_\_\_, and the source of each abstract is indicated thereon.
  - [ ] documents \_\_\_\_\_ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

Foreign Lang. Doc.# English Lang. Doc.# [insert]

- [ ] applicants have prepared an English translation of at least the pertinent portions of documents \_\_\_\_\_\_, and copies are attached.
- [] A concise explanation of the relevance of documents \_\_\_\_\_\_ is found in the attached search report from the \_\_\_\_\_ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [] A concise explanation of the relevance of documents \_\_\_\_\_ is set forth as follows:

  [Insert concise explanation of relevance]

  [X] A concise explanation of the relevance of document(s) AL can be found on page(s) 13 of the specification.
- 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
  - 5. Other information being provided for the examiner's

consideration follows:

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[insert other information]

- 6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in \$1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.
- 7. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C. Attorneys for Applicant

By:

Tver P. Cooper Reg. No. 28,005

624 Ninth Street, N.W. Washington, D.C. 20001 Telephone: (202)628-5197 Facsimile: (202)737-3528

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Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE	Application Number	09/845,716	
STATEMENT BY APPLICANT	Filing Date	May 2, 2001	
(use as math( sheets as necessary)	First Named Inventor	Soren NIELSEN	
	Group Art Unit		
( OCT 0 1 2001 ()	Examiner Name		
Sheet 1 S of 2	Attorney Docket Number	NIELSEN3A	
MADEMARIE			

U.S. PATENT DOCUMENTS						
	Cite No.1				Date of Publication of	Pages, Columns, Lines,
	INO.	Number known)	Kind Code <sup>2</sup> (if	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear
	AA	50,28592		LIPTON	07-02-1991	
	АВ	5731408		HADLEY, et al.	03-24-1998	
	AC	5830994		D'HINTERLAND, et al.	11-03-1998	
	AD	5835382		WILSON, et al.	11-10-1998	
	AE	5986047		WRIGHTON, et al.	11-16-1999	
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FOREIGN PATENT DOCUMENTS								
Examiner Cit Initials* No	Cite		U.S. Patent Document		Name of Patentee or Applicant	Date of Publication of	Pages, Columns, Lines,	
	NO.	Office <sup>3</sup>	Number	Kind Code <sup>5</sup> (if known)	of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	AF	wo	8704623		UNIVERSITY PATENTS INC.	08-13-1987		
	AG	wo	8800833		BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM	02-11-1988		
•	АН	wo	9641815		DUSSOURD D'HINTERLAND	12-27-1996		
	Al	wo	9921571		TREGA BIOSCIENCES, INC.	05-06-1999		
	AJ	wo	9957148		WA PHARM AB	11-11-1999		
	AK	wo	0032772		ELI LILLY AND CO.	06-08-2000		
	AL	EP	0972522		L'OREAL-DPI	01-19-2000		

Examiner	Date	
Signature	Considered	

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE	Application Number	09/845,716	
STATEMENT BY APPLICANT	Filing Date	May 2, 2001	
(use as many sheets as necessary)	First Named Inventor	Soren NIELSEN	
OCT 0 1 2001 H	Group Art Unit		
\.3	Examiner Name		
Sheet 2 of 2	Attorney Docket Number	NIELSEN 3A	

		OTUED DRIOD ART. MON PATENT LITERATURE DOCUMENTS	
	1	OTHER PRIOR ART- NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	АМ	RAJORA, et al., α-MSH Modulates Experimental Inflammatory Bowel Disease, Peptides, 1997, 381-385, 18(3)	
	AN	STAR, et al., Evidence of Autocrine Modulation of Macrophage Nitric Oxide Synthase by α-melanocyte-stimulating Hormone, Proc. Natl. Acad. Sci. USA, 1995, 8016-8020, 92	
	AO	SADAMOTO, et al., Erythropoietin Prevents Place Navigation Disability and Cortical Infarction in Rats with Permanent Occlusion of the Middle Cerebral Artery, Biochemical and Biophysical Research Communications, 1998, 26-32, 253	
-	AP	SAKANAKA, et al., In vivo Evidence that Erythropoietin Protects Neurons from Ischemic Damage, Proc. Natl. Acad. Sci. USA, 1998, 4635-4640, 95	
	AQ	SQUANDRITO, et al., Recombinant Human Erythropoietin Inhibits iNOS Activity and Reverts Vascular Dysfunction in Splanchnic Artery Occlusion Shock, British Journal of Pharmacology, 1999, 482-488, 127	
	AR	SQUADRITO, et al., Adrenocorticotropin Reverses Vascular Dysfunction and Protects Against Splanchnic Artery Occlusion Shock, British Journal of Pharmacology, 1999, 816-822, 128	
	AS	CHIAO, et al., α-Melanocyte-stimulating Hormone Protects Against Renal Injury after Ischemia in Mice and Rats, J. Clin. Invest., 1997, 1165-1172, 99(6)	
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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.